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MEMORANDUM

May 26, 2005

Via E-Mail

RE: FSIS Federal Register Notice on Mechanically Tenderized Beef

In today's Federal Register, the Food Safety and Inspection Service (FSIS) published a Notice mandating that establishments producing non-intact beef products reassess their HACCP plans to ensure their food safety systems adequately address *E. coli* O157:H7 in light of the foodborne outbreaks involving such products. 70 Fed. Reg. 30331.

<http://www.fsis.usda.gov/OPPDE/rdad/FRPubs/04-042N.pdf>

This reassessment can be conducted as part of the establishment's annual reassessment (to the extent the establishment has not already conducted a reassessment taking the outbreaks into account). If the establishment has already conducted its annual reassessment for 2005, it can consider the outbreaks in its 2006 reassessment.

We note that the current Federal Register Notice is similar to the Notice published on October 7, 2002 requiring that all establishments producing any raw beef reassess their HACCP programs based on scientific data concerning the prevalence of *E. coli* O157:H7.

Applicability – The Notice applies to any establishment that produces raw or cooked products that have been processed in a manner by which surface contamination could be transferred to the internal portions, *i.e.*, non-intact products. This would include injected products as well as mechanically tenderized.

Factors an Establishment Should Consider – The Notice identifies certain issues that an establishment should consider with regard to control of *E. coli* O157:H7:

- The establishment may evaluate the adequacy of the interventions being applied to the source materials (*e.g.*, subprimals).
- The establishment may adopt purchase specifications requiring the incoming products be treated to reduce *E. coli* O157:H7 to below detectable levels. These specifications could be part of the establishment's HACCP plan, SSOPs or a

prerequisite program, but regardless of where the specifications appear, the establishment should verify supplier compliance with such specifications.

- The establishment may consider applying an antimicrobial agent to the raw materials.
- The establishment should review its sanitation practices taking into account the possibility of cross contamination by the tenderizing/injection equipment.
- FSIS also suggests that establishments consider specific cooking instructions for raw, non-intact products in addition to safe handling instruction, (e.g., cook to an internal temperature of x°) However, such labeling could not be deemed to be a CCP.

For cooked products

- FSIS suggests the establishment re-affirm that its cooking instructions are adequate. The Notice includes a summary of research done on this issue.

Guidance Material – The Notice references a guidance document created in connection with the 2002 Notice concerning antimicrobials. The document can be found at: http://www.fsis.usda.gov/Frame/FrameRedirect.asp?main=http://www.fsis.usda.gov/OPP/DE/rdad/FRPubs/Docs_00-022N.htm. In addition, the agency provides a summary of other scientific materials to assist establishments near the end of the Notice.

Further Agency Actions –

FSIS will be preparing a Notice for its inspection force describing how the inspector is to verify that the establishment has conducted the reassessment.

FSIS is considering requiring special labeling of non-intact raw products to inform the consumer that the product has been injected/tenderized and that such products must be cooked to an adequate internal temperature to “destroy any pathogens that may have been translocated from the surface of the product to the interior.”

Comments – FSIS will accept comments on the Notice until July 25, 2005.

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We will continue to monitor this issue for you. If you have any questions or desire additional information, please do not hesitate to contact us.

OFW:drj